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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,600	03/11/1999	YAROM COHEN	TPP30566	7243

7590 01/29/2004

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WASHINGTON, DC 20036

EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/254,600

Applicant(s)

COHEN, YAROM

Examiner

Anish Gupta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 110-115, 117 and 118 is/are pending in the application.
- 4a) Of the above claim(s) 117 and 118 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 110-115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 11-6-03 has been entered.

Election Restriction

1. Applicant's election of Cyclo [N-Me-Ala-Tyr-D-Trp-Lys-Val-Phe] in Paper No. 17 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Although the Applicants did not specifically as such, the elected species reads on claims 110-115. Claims 117 and 118 drawn to diazoxide and metformin are hereby withdrawn. Note that claim 117-118 were indicated as being part of the elected species in the previous office action. This was an oversight. The election was for a somatostatin analog and all arguments were drawn to somatostatin analogs. Claim 117-118 are drawn to diazoxide and metformin which are structurally distinct from somatostatin. Thus, the claims should have been withdrawn in the previous office action. The narrative of the rejection is now correctly reflective of the original election.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 110-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mogul et al. and Reaven in view of Orskov et al. and Verber et al for the reasons set forth in the previous office action and the reasons set forth below

The claims are drawn to a method of treating Syndrome X to a patient exhibiting symptoms of Syndrome X by the administration of somatostatin.

Applicants argue that the claims are amended to recite the treatment of syndrome X rather than the symptoms of syndrome X. The reference combined do not teach nor suggest the treatment of Syndrome X but only the symptoms of syndrome X.

Applicant's arguments filed 11-6-03 have been fully considered but they are not persuasive.

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On page 2 of the specification it is stated:

“All of the risk factors of syndrome X of Reaven are, inter alia, caused by a high resistance to Insulin. Thus, apparently said symptoms could be treated simultaneously if there would be reduction of the resistance to Insulin. . .

We have now found that due to the fact that the reduction of the resistance to Insulin can be achieved by administration of a compound selected among somatostatin or its analogs (as herein defined), diazoxide or one of its analogs (as herein defined), cyclothiazide or one of its analogs (as herein defined and metformin, said treatment may enable the treatment of all risk factors of syndrome X of Reaven simultaneously.”

Thus, controlling the resistance of insulin, “enable the treatment of all risk factors of syndrome X or Reaven simultaneously.” As stated in the previous office action the reference of Mogul et al. teach that “[h]yperinsulinemia is a manifestation of insulin resistance, a precursor to non-insulin diabetes mellitus (NIDDM) and the hallmark of Metabolic Syndrome X.” (See page 4492). The art recognizes that somatostating and octreotide infusion decreased insulin requirement and increased insulin sensitivity in IDDM patients (see Orskov et al. at page 215). Therefore, since the art recognizes that insulin resistance is the hallmark of Syndrome X, it would have been obvious to use somatostatin to control insulin resistance, and thereby treat Syndrome X. Controlling insulin resistance would necessarily lead to the treatment of Syndrome X since all of the risk factors are connected to the treatment of insulin resistance.

Therefore, the rejection is maintained.

3. The rejection of claims 110-115 and 117-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reaven in view of Carretta et al. and Verber et al. is hereby withdrawn in view of the claimed amendments.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)-272-0965. If attempts to

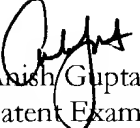
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reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

 1/14/04
Anish Gupta
Patent Examiner